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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,010	DILLON, MARK E.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-49* is/are pending in the application.

4a) Of the above claim(s) *46-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 12/27/05 is acknowledged. Claims **34-49** are pending in this application. Claims 46-49 are withdrawn as being drawn to a non-elected invention. Claims 1-33 stand cancelled.

Election/Restrictions

Newly submitted claims 46-49 drawn to a method of manufacturing a wound dressing, classified in class 427, subclass 389.9, directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case invention I (originally presented invention) can be made by a different process without the use of an adhesive layer to bond the layers whereas invention II requires the use of an adhesive layer to bond the first and second layer.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-49 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is directed to the first layer being "substantially transparent". The term "substantially" in claim 41 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Further claim 41 recites "the adhesive layer containing a pigment for imparting a discernible color to the first layer of the wound dressing" which is vague and indefinite since it is unclear how the adhesive layer comprising a pigment would impart a color to another separate layer. Further, it is unclear how the first layer can be "substantially transparent" and yet have a discernible color that is imparted by the pigment of the adhesive layer. Thus, how can a layer be transparent and yet have a discernible color since the definition of transparent is the lack of color. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 34-37 and 44-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,051,747).

Lindqvist et al disclose a wound dressing comprising a gel layer (3) with a thickness of 0.2-2mm (200-2000 microns) and a polyurethane foam layer (2) with open cells (fenestrations) and a thickness of 1-10mm (1000microns to 10,000 microns). See Figure 2. The gel layer is made of a skin adhering silicone gel (polydimethylsiloxane gel). See column 5, lines 45-65 and column 3, lines 25-30. Lindqvist discloses that the foam functions as an absorbent layer and the gel functions to prevent wound fluid from running over healthy skin and functions to soften the horny layer. See column 3, lines 25-38. Note that the gel layer in this embodiment reads on the instant membrane layer since "membrane" is defined as "a thin sheet of natural or synthetic material".

Lindqvist also discloses a wound dressing comprising a gel layer (3), a polyurethane foam layer with open cells (2), and a liquid impervious layer made of a polyurethane film (5). See column 22, line 65 to column 3, line 2. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. Note that the gel layer or the polyurethane film in this embodiment read on the instant membrane layer since "membrane" is defined as "a thin sheet of natural or synthetic material". Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

With regard to lines 4-9 of independent claim 34, it is the examiner's position that since Lindqvist discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not

structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues that although Lindqvist discloses a gel layer and an absorbent foam, Lindqvist does not suggest or discloses a dual purpose wound dressing with disparate would healing characteristic. Applicant argues that Lindqvist disclose the surface is covered b a liquid impervious layer.

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The examiner points out that the prior art discloses a 1) polymeric gel layer and 2) a polyurethane foam layer in Figure 2. Thus, since Lindqvist's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use. The examiner further points out that Lindqvist also clearly discloses the purpose of each layer wherein the gel layer is taught to seal the wound and soften the horny layer and the foam layer is taught to absorb wound fluid. Thus, the wound dressing of Figure 2 is clearly capable of performing the instant intended use.

The examiner also points out that Lindqvist's alternative embodiment, i.e. Figure 1, reads on the instant invention. It is the examiner's position that the polyurethane film in Figure 1 also reads on the membrane layer.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).

Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel (see column 2, lines 44-45) and a carrier material. Example 5 discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam. Hofeditz discloses the additional use of dyes and pigments. See claim 13 and examples.

It should be noted that membrane is defined as a "thin, soft pliable sheet or layer"; thus Hofeditz polymeric gel layer reads on "membrane layer".

With regard to lines 4-9 of independent claim 34, it is the examiner's position that since Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues that the instant invention is directed to novel wound dressing that has disparate wound healing properties depending on which side of the wound dressing contacts the wound. Applicant argues that Hofeditz does not teach this.

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer.

The examiner points out that the prior art discloses a 1) polymeric membrane layer and 2) a polyurethane foam layer. Thus, since Hofeditz's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use.

Claims 34-36, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).

Freeman discloses a polymeric support wound dressing which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The adhesives disclosed are natural rubber, silicone rubber, polyurethane rubber, and polyisotbutene rubber. See column 6, lines 30-32. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

It should be noted that membrane is defined as a "thin, soft pliable sheet or layer"; thus Freeman's perforated polymeric support reads on instantly claimed "membrane layer".

With regard to lines 4-9 of independent claim 34, it is the examiner's position that since Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues that the instant invention is directed to novel wound dressing that has disparate wound healing properties depending on which side of the wound dressing contacts the wound. Applicant argues that Freeman teaches away from this since the occlusive layer is open to the atmosphere and does not contact the wound..

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. Applicant's arguments are unclear. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer or 1) a membrane layer, 2) adhesive layer, and 3) a foam layer. The examiner points out that the prior art discloses a 1) polymeric membrane layer, 2) an adhesive layer, and 3) a polyurethane foam layer. Thus, since Freeman's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use. The examiner further points out that the instant disclosure states that using the instant invention "upside down" provides the dual purpose; thus Freeman's dressing is also capable of being turned "upside down" to provide the dual function.

Applicant discloses on page 5, lines 22-25:

"By applying the dressing to the wound site with the IPN surface against the wound surface...."

On page 6, lines 4-12, applicant discloses:

"I have discovered that the dressing...is also useful when used up-side down with the foam layer against the wound instead of the IPN layer."

The examiner notes that depending on which side one desires to contact the wound, the dressing is flipped accordingly. For instance, if one desired the first layer to contact the wound,

then the foam layer would not be in contact with the wound simultaneously and would also in fact be "open to the atmosphere"; thus applicant's arguments are perplexing

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421).

As set forth above, Lindqvist et al disclose a wound dressing comprising a gel layer (3) with a thickness of 0.2-2mm (200-2000 microns) and a polyurethane foam layer with open cells (fenestrations) and a thickness of 1-10mm (2). See Figure 2. The gel layer is made of a skin adhering silicone gel (polydimethylsiloxane gel). See column 5, lines 45-65 and column 3, lines 25-30. Lindqvist discloses that the foam functions as an absorbent layer and the gel functions to prevent wound fluid from running over healthy skin and functions to soften the horny layer. See

column 3, lines 25-38. Note that the gel layer in this embodiment reads on the instant membrane layer since "membrane" is defined as "a thin sheet of natural or synthetic material".

Lindqvist also discloses a wound dressing comprising a gel layer (3), a polyurethane foam layer with open cells (2), and a liquid impervious layer made of a polyurethane film (5). See column 22, line 65 to column 3, line 2. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. Note that the gel layer or the polyurethane film in this embodiment read on the instant membrane layer since "membrane" is defined as "a thin sheet of natural or synthetic material". Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Lindqvist also does not teach the use of a pigment in the gel layer.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film in embodiment 2 with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in Lindqvist's wound dressing versus Lindqvist's polyurethane film, if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

With regard to claim 40, it would have been obvious to add a pigment to the silicone gel of Lindqvist if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

With regard to claim 41, note the 112, 2nd rejection. It should be additionally noted that polymeric film layers are implicitly translucent unless a pigment is added. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

Response to Arguments

Applicant argues that Lindqvist is directed to a hydrophobic gel and Lorenz is directed to a hydrophilic gel. Further, applicant argues that Lorenz does not teach a foam layer.

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case, applicant has not addressed the examiner's motivation to combine the references and has rather analyzed each reference separately. The examiner points out that the primary reference is not deficient in the teaching of a foam layer and thus Lorenz does not need to teach a foam layer. The premise of the rejection is the motivation to substitute Lindqvist's polyurethane film in embodiment 2 with the instant IPN film. Applicant has not provided any arguments or evidence of the unobvious difference. With regard to the primary reference teaching a hydrophobic gel while the secondary reference teaches a hydrophilic gel, this is not the premise of the rejection and it is irrelevant.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) in further view of Cartmell et al (5,160,328).

The teachings of Lindqvist et al and Lorenz et al have been set forth above.

The references do not teach the use of fenestrations in the layer.

Cartmell teaches a hydrogel bandage for wounds. Cartmell teaches that the bandage is formed from materials which permit the transmission of air and vapor so as to facilitate further

the healing of the wound. Cartmell teaches that the materials may also be perforated or scored with holes or apertures to readily permit the passage of air and vapor. In this way, bacterial proliferation and the formation of incrustations in the wound are minimized. See column 5, lines 35-45.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al, Lorenz et al, and Cartmell et al and perforate the layers of the device. One would have been motivated to do so since Cartmell teaches the passage of air and vapor is crucial for the healing process and by perforating the layers, bacterial proliferation and incrustations are prevented. Therefore, a skilled artisan would have been motivated to perforate the layers to further contribute to the healing process.

Response to Arguments

Applicant argues that Cartmell teaches a hydrogel which does not have a dual purpose. Applicant argues that Cartmell only teaches a single sided wound contacting surface.

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case, again the applicant has not addressed the examiner's motivation to combine the references and has rather analyzed each reference separately. Applicant argues intended use of each of the references and the examiner points out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421).

As set forth above, Freeman discloses a polymeric support wound dressing which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The adhesives disclosed are natural rubber, silicone rubber, polyurethane rubber, and polyisotbutene rubber. See column 6, lines 30-32. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-

polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing Therefore, a skilled artisan would have been motivated to utilize the instant polymer film in Lindqvist's wound dressing if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

With regard to the claims 40-41, it should be additionally noted that polymeric film layers are implicitly translucent unless a pigment is added. Thus, Freeman's polymeric support layer would implicitly be "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to *any* layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

Additionally with regard to claim 41, the 112, 2nd rejection should be noted.

Response to Arguments

Applicant argues that it would not have been obvious to combine the references and even if the references are combined the instant invention is not taught.

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. The merits of Freeman have been discussed above under the anticipation rejection and thus the examiner's response to applicant's arguments are incorporated herein. Applicant does not specifically address the instant combination and thus it is the examiner' s position that the instant invention is prima facie obvious for the reasons stated in the above rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER